IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

DEBORAH SCHRECENGOST and ROGER SCHRECENGOST,	)	Case No. 3:17-cv-220
Plaintiffs,	)	JUDGE KIM R. GIBSON
v.	)	
COLOPLAST CORPORATION and COLOPLAST MANUFACTURING US, LLC,	)	
Defendants.	)	

MEMORANDUM OPINION

I. Introduction

This case arises from Plaintiff Deborah Schrecengost's alleged injuries resulting from complications from a surgery to treat her stress urinary incontinence ("SUI") with Defendants' Aris Transobturator Sling System ("Aris"), a prescription-only surgical mesh implant. Pending before the Court are Defendants' Motion to Exclude Opinions and Testimony of Dr. Grant Campbell (ECF No. 61), Motion to Strike Plaintiffs' Proposed Sur-Reply and to Exclude from Trial the Untimely Expert Opinions of Dr. Michael Margolis (ECF No. 93), and Motion for Summary Judgment. (ECF No. 63.) The Motions are fully briefed (ECF Nos. 62, 64, 70, 73, 79, 80, 92, 94, 98-1, 102) and ripe for disposition. For the reasons that follow, the Court **DENIES** Defendants' Motions.

II. Jurisdiction and Venue

This Court has subject-matter jurisdiction because the parties are diverse and the amount in controversy exceeds $75,000. 28 U.S.C. § 1332. Venue is proper because the case was

transferred to the Western District of Pennsylvania, where a substantial part of the events giving rise to Plaintiff's claims occurred. 28 U.S.C. § 1391(b)(2), § 1404(a).

III. Factual Background

The following facts are undisputed unless otherwise noted.[1]

A. Mrs. Schrecengost's Surgery

On November 3, 2008, Dr. Jeffrey David performed pelvic reconstructive surgery on Mrs. Schrecengost at Armstrong County Memorial Hospital in Kittanning, Pennsylvania, during which he implanted Coloplast's Aris to treat her SUI. (ECF No. 81 ¶ 1.) Aris is an FDA-cleared, prescription-only surgical mesh implant indicated for pelvic reconstructive surgery, including the procedure Dr. David performed on Mrs. Schrecengost. (*Id.* ¶ 2.) The Aris is the only surgical mesh implant Dr. David has ever used to treat female SUI and he still uses it to surgically treat SUI. (*Id.* ¶¶ 3–4.) Because the Aris implant surgery is an elective surgery, not an emergency surgery, Dr. David stated that he would mention any extraordinary risks to his patients. (*Id.* New Matter ¶ 6.)

Defendants assert, and Plaintiffs deny, that prior to performing her November 3, 2008 surgery, Dr. David consulted with Mrs. Schrecengost three times regarding the potential risks of

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[1] The Court derives these facts from a combination of Defendants' Concise Statement of Undisputed Material Facts in Support of Their Motion for Summary Judgment (ECF No. 65), Plaintiffs' Response to Defendants' Concise Statement of Facts in Support of Their Opposition to Defendants' Motion for Summary Judgment (ECF No. 72-2), Defendants' Reply to Plaintiffs' Response to Defendants' Concise Statement of Material Facts in Further Support of Their Motion for Summary Judgment and Response to Plaintiffs' Concise Statement of Facts (ECF No. 81), Plaintiffs' Supplemental Statement of Material Facts Regarding Dr. Michael Thomas Margolis's Expert Report and His Examination of Deborah Schrecengost (ECF No. 104), Defendants' Response to Plaintiffs' Supplemental Statement of Material Facts Regarding Dr. Margolis (ECF No. 109). When referring to the New Matter Plaintiffs raise in response, the Court will refer to it as (ECF No. 81 New Matter) with the appropriate reference.

using the Aris to treat her SUI, specifically warning her about dyspareunia, which is painful sexual intercourse, and chronic pelvic pain. (*Id.* ¶ 6.) Defendants assert that Dr. David had no recollection of reading or referring to the Aris Instructions for Use ("IFU") prior to performing Mrs. Schrecengost's 2008 surgery; Plaintiffs respond that Dr. David reviewed the Aris IFU prior to Mrs. Schrecengost's surgery and relied on the directions and warnings that came with the Aris. (*Id.* ¶ 7.) Dr. David testified that he relies in part on the warnings he receives from Defendants with their devices and that the warnings should list any complication with the frequency or severity that has some impact on the risk and benefit discussion that doctors have with their patients. (*Id.* New Matter ¶¶ 11–12.) Defendants assert that Mrs. Schrecengost gave her informed consent to proceed with the 2008 surgery. (*Id.* ¶ 8.) Plaintiffs state that although Mrs. Schrecengost signed the consent form, Dr. David did not warn her of the risk that the Aris mesh could degrade over time. (*Id.*)

On August 23, 2016, Dr. Michael Bonidie performed a resection of Mrs. Schrecengost's Aris at University of Pittsburgh Medical Center because she was experiencing pain. (*Id.* ¶¶ 9–10.) Defendants assert that Dr. Bonidie found no evidence that Mrs. Schrecengost's Aris had become infected or exposed, or that it had eroded, extruded, or degraded. (*Id.* ¶ 11.)

B. Medical Risks of the Aris

Plaintiffs assert that Defendants had paid consultants who expressed concerns about safety issues associated with the Aris and that Defendants failed to include significant risks in its IFU related its products, including injury in the form of life-long, late infections. (*Id.* New Matter ¶¶ 7–8.) Plaintiffs assert that Coloplast significantly downplayed the risks that it listed in its IFU and that the IFUs did not include sufficient information to advise physicians on the permanence,

frequency, or severity of the complications that can arise from the use of its devices. (*Id.* New Matter ¶¶ 9–10.)

Plaintiffs assert that Defendants' internal company documents and company witnesses confirm that Defendants knew of the risks and complications associated with the Aris yet continued to market and sell the device. (*Id.* New Matter ¶ 14.) At a 2008 Women's Health Advisory Board Meeting, several doctors warned Defendants about the use of heavier weight mesh, like the kind used in the Aris, and its relationship to increased erosion rates. (*Id.* New Matter ¶ 21.) Dr. Bruce Rosenzweig testified to the potential dangers of the heavy-weight, small pore polypropylene mesh Defendants used in the Aris, calling the devices "unreasonably dangerous." (*Id.* New Matter ¶ 20.) Plaintiffs assert that the effects of chemical and biological degradation of the mesh in a woman's tissues can lead to a greater foreign body reaction, enhanced inflammatory response, and excessive scarring, which can lead to severe complications in patients, like Mrs. Schrecengost's complications. (*Id.* New Matter ¶¶ 4–5.)

Additionally, Plaintiffs assert that Defendants knew that lighter weight mesh alternatives existed prior to November 2008. (*Id.* New Matter ¶ 17.) Plaintiffs assert that Defendants had an opportunity to purchase "gold standard" mini-sling intellectual property that had the potential to reduce or eliminate adverse risks to patients, but that they failed to implement these alternative designs. (*Id.* New Matter ¶ 15.) Plaintiffs assert that the Ultrapro, a similar medical device, is an example of a safer alternative design for use in the treatment of SUI in women. (*Id.* New Matter ¶ 18.)

Mrs. Schrecengost testified that if she had been informed of the true risks associated with the Aris, such as permanent vaginal pain, permanent pelvic pain, and permanent dyspareunia, she would not have consented to the Aris implantation surgery. (*Id.* New Matter ¶ 13.)

C. Mrs. Schrecengost's Post-Resection Medical Examinations

On February 7, 2019, Dr. Grant Campbell, M.D., an obstetrician and gynecologist, performed a medical exam on Mrs. Schrecengost. (ECF No. 66-13 at 1.) He issued a report on February 28, 2019, opining that the Aris caused Mrs. Schrecengost's pelvic injuries. (ECF No. 66-12 at 5.) Dr. Campbell reached his conclusion by performing a differential diagnosis, which involved looking at Mrs. Schrecengost's symptoms and ruling out possible alternative causes of her symptoms to determine the cause. (*See id.*)

In late August 2019, Mrs. Schrecengost reported to Plaintiffs' counsel that her symptoms had increased in severity since her February 2019 visit with Dr. Campbell, reporting a recent onset of heavy vaginal bleeding and increased pain.[2] (ECF No. 104 ¶ 1.) Dr. Michael Margolis, M.D., a board certified urogynecologist, performed an independent medical exam of Mrs. Schrecengost on September 3, 2019. (*Id.* ¶ 2.) At mediation on September 18, 2019, Plaintiffs' counsel advised defense counsel that Mrs. Schrecengost had a change in condition with worsening symptoms and that Mrs. Schrecengost had been examined by a potential new expert who was going to issue a report after reviewing Mrs. Schrecengost's medical records. (*Id.* ¶ 4.) Plaintiffs' counsel also offered Defendants the opportunity to perform their own medical examination of Mrs. Schrecengost. (*Id.*)

[2] Defendants deny most of Plaintiffs' statements regarding Dr. Margolis. (*See* ECF No. 109.)

On October 2, 2019, Dr. Margolis issued an expert report detailing his physical examination of Mrs. Schrecengost and discussing his opinions that the Aris sling contributed to her injuries. (*Id.* ¶ 5.) In his report, Dr. Margolis noted injuries attributable to the Aris sling which were developing but not yet present during Dr. Campbell's examination eight months earlier. (*Id.* ¶ 7.) On October 16, 2019, Plaintiffs disclosed Dr. Margolis as an expert. (*Id.* ¶ 6.) Since the disclosure, Mrs. Schrecengost has seen, or is scheduled to be seen by, doctors on multiple dates throughout October and November of 2019 regarding her pelvic pain. (*Id.* ¶ 18.)

IV. Procedural Background

On August 31, 2017, Plaintiffs filed the Complaint (ECF No. 1), in the United States District Court for the Eastern District of Pennsylvania. On November 20, 2017, that court transferred the case to this Court (ECF No. 12), and the Defendants filed their Answer on December 4, 2017 (ECF No. 14). On June 14, 2019, the parties stipulated to a dismissal with prejudice of nine counts in the Complaint, and three further counts on October 28, 2019, leaving only the claims for Strict Liability – Defective Design (Count I); Strict Liability – Failure to Warn (Count II); Negligence (Count III); and Loss of Consortium (Count XIV). (*See* ECF Nos. 59, 60, 96, 97.)

Defendants moved to exclude the opinions and testimony of Dr. Grant Campbell on June 21, 2019, and moved for summary judgment that same day. (ECF Nos. 61, 63.) Plaintiffs responded in opposition to both motions on July 22, 2019 (ECF Nos. 69, 72), to which Defendants replied on July 31, 2019. (ECF No. 79, 81.) Plaintiffs filed a Sur-Reply on October 22, 2019 (ECF No. 92), which Defendants moved to strike on October 24, 2019 (ECF No. 93). Plaintiffs responded in opposition to the Motion to Strike on October 30, 2019 (ECF No. 98), to which Defendants replied on November 6, 2019. (ECF No. 102.)

V. Legal Standards

A. Expert Opinion

Under the Federal Rules of Evidence, a trial judge acts as a "gatekeeper" to ensure that "any and all expert testimony or evidence is not only relevant, but also reliable." *Pineda v. Ford Motor Co.*, 520 F.3d 237, 244 (3d Cir. 2008) (quoting *Kannankeril v. Terminex Int'l, Inc.*, 128 F.3d 802, 806 (3d Cir. 1997)). Therefore, when a party seeks to admit expert testimony, the Court must make a preliminary determination that the proffered expert meets the requirements of Rule 702. *Magistrini v. One Hour Martinizing Dry Cleaning*, 68 F. App'x 356, 356 (3d Cir. 2003) (citing *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 592 (1993)). Rule 702 allows a qualified expert to testify in the form of an opinion if:

> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702(a).

The Third Circuit has interpreted Rule 702 as having three major requirements. *Pineda*, 520 F.3d at 244. First, the proffered witness must be qualified as an expert. *Id.* Second, the expert must testify about matters requiring scientific, technical, or specialized knowledge and base his or her opinions on reliable processes and techniques. *Id.* Third, the expert's testimony must assist the trier of fact. *Id.* The party offering the expert must prove each of these requirements by a preponderance of the evidence. *Mahmood v. Narciso*, 549 F. App'x 99, 102 (3d Cir. 2013) (citing *In re TMI Litig.*, 193 F.3d 613, 663 (3d Cir. 1999)).

Rule 702 has "a liberal policy of admissibility." *Pineda*, 520 F.3d at 243 (citing *Kannankeril*, 128 F.3d at 806). Exclusion of expert testimony is the exception rather than the rule because "vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." Fed. R. Evid. 702 advisory committee's note to 2000 amendment (citing *Daubert*, 509 U.S. at 595).

B. Summary Judgment

This Court will grant summary judgment "if the movant shows there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); *Melrose, Inc. v. Pittsburgh*, 613 F.3d 380, 387 (3d Cir. 2010) (quoting *Ruehl v. Viacom, Inc.*, 500 F.3d 375, 380 n.6 (3d Cir. 2007)); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). There is a genuine issue of fact "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986); *see also McGreevy v. Stroup*, 413 F.3d 359, 363 (3d Cir. 2005). Material facts are those that affect the outcome of the trial under governing law. *Anderson*, 477 U.S. at 248. The Court's role is "not to weigh the evidence or to determine the truth of the matter, but only to determine if the evidence of record is such that a reasonable jury could return a verdict for the nonmoving party." *Am. Eagle Outfitters v. Lyle & Scott Ltd.*, 584 F.3d 575, 581 (3d Cir. 2009). In deciding a summary judgment motion, this Court "'must view the facts in the light most favorable to the nonmoving party and draw all inferences in that party's favor.'" *Farrell v. Planters Lifesavers Co.*, 206 F.3d 271, 278 (3d Cir. 2000) (quoting *Armbruster v. Unisys Corp.*, 32 F.3d 768, 777 (3d Cir. 1994)).

The moving party bears the initial responsibility of stating the basis for its motion and identifying those portions of the record that demonstrate the absence of a genuine issue of material fact. *Celotex*, 477 U.S. at 323. If the moving party meets this burden, the party opposing summary judgment "may not rest upon the mere allegations or denials" of the pleading, but "must set forth specific facts showing that there is a genuine issue for trial." *Saldana v. Kmart Corp.*, 260 F.3d 228, 232 (3d Cir. 2001) (quoting *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 n.11 (1986)). "For an issue to be genuine, the nonmovant needs to supply more than a scintilla of evidence in support of its position—there must be sufficient evidence (not mere allegations) for a reasonable jury to find for the nonmovant." *Coolspring Stone Supply v. Am. States Life Ins. Co.*, 10 F.3d 144, 148 (3d Cir. 1993); *see also Podobnik v. U.S. Postal Serv.*, 409 F.3d 584, 594 (3d Cir. 2005) (noting that a party opposing summary judgment "must present more than just bare assertions, conclusory allegations or suspicions to show the existence of a genuine issue").

VI. Discussion

A. The Court Denies Defendants' Motion to Exclude Opinions and Testimony of Dr. Grant Campbell

1. The Parties' Arguments

Defendants first argue that the Court should exclude Dr. Campbell's testimony because he lacks a reliable foundation and methodology to support any opinion he offers about the cause of Mrs. Schrecengost's alleged injuries.[3] (ECF No. 62 at 9–10.) Defendants assert that because Dr.

[3] It is within the discretion of a district court to determine whether a *Daubert* hearing is necessary to determine if a proffered expert's testimony satisfies Rule 702. *See Padillas v. Stork-Gamco, Inc.*, 186 F.3d 412, 417–18 (3d Cir. 1999). Here, the Court finds that it is unnecessary to hold a hearing on the admissibility of Plaintiffs' proffered expert testimony. The parties did not request a *Daubert* hearing and the Court is satisfied that the briefing on the expert testimony in this case is sufficient to decide the Motion.

Campbell did not review any of Mrs. Schrecengost's medical history predating the implantation of her Aris, his opinion about the causes of her current alleged injuries is unreliable. (*Id.* at 10–11.) After Dr. Campbell saw Mrs. Schrecengost's medical records at his deposition, he testified that he could no longer opine with medical certainty that the Aris had caused some of her complaints. (*Id.* at 14.) Defendants contend that there is no possible way that Dr. Campbell could have reliably concluded that Mrs. Schrecengost's Aris implant was the sole or primary cause of all of her alleged injuries because Dr. Campbell did not review her medical history either before he wrote his report or when Defendants deposed him.[4] (*Id.* at 15.)

Defendants next argue that the Court should exclude Dr. Campbell from testifying because his report does not satisfy the requirements of Rule 26(a) because it fails to list his qualifications or publications, include the necessary list of his prior case testimony, or provide his rate of compensation. (*Id.* at 17.) Defendants assert that Dr. Campbell should not be able to file an amended or supplemental report because the deadline for expert disclosures has already passed. (*Id.* at 16.)

Plaintiffs assert that Dr. Campbell's opinion is reliable because he reviewed all of the records provided to him, including Mrs. Schrecengost's medical records, as his report indicates. (ECF No. 70 at 4–6.) Plaintiffs contend that Dr. Campbell considered the contents of each of the records when performing his differential diagnosis and argue that whether he could recall certain

[4] Defendants also assert that this Court should preclude Dr. Campbell from offering opinions that he has testified that he will not offer or can no longer reliably offer. (ECF No. 62 at 15.) Plaintiffs state that Dr. Campbell will not offer opinions inconsistent with his prior testimony and will not offer opinions on subjects for which he is not an expert. (ECF No. 70 at 12.) Because experts may supplement or amend their reports up to 30 days before trial under Rule 26, the Court holds that this request is premature and denies it without prejudice.

records at his deposition is not relevant to the reliability of his opinion. (*Id.* at 5–6.) Specifically, that Dr. Campbell was aware of Mrs. Schrecengost's prior history of dyspareunia from the 1990s and that he determined that those complaints were resolved before her Aris implant surgery. (*Id.* at 8.) He also ruled out her history of endometriosis, pelvic relaxation, and vaginal lacerations as possible causes of her current dyspareunia. (*Id.* at 10–12.) Plaintiffs assert that because the record shows that Dr. Campbell relied on these records in preparing his expert report, his opinions and testimony are reliable and admissible. (*Id.* at 2.)

Plaintiffs next argue that whether an expert may file a supplemental report is not a proper subject for a *Daubert* motion because it does not speak to the relevancy or reliability of Dr. Campbell's opinion. (*Id.* at 13.) Under Rule 26, Dr. Campbell has until 30 days before trial to supplement his expert disclosures. (*Id.*) Plaintiffs further argue that any errors or omissions in his expert disclosure were harmless, have already been cured, and do not warrant exclusion of Dr. Campbell's report because Defendants now possess Dr. Campbell's testimonial history and fee schedule and that this information was not withheld in bad faith. (*Id.* at 14–16.)

2. The Court Holds that Dr. Campbell's Expert Opinion Is Reliable

The parties contest only the reliability of Dr. Campbell's differential diagnosis opinion. Defendants do not challenge the differential diagnosis methodology, but instead argue that Dr. Campbell did not reliably apply the differential diagnosis methodology to the facts of the case. For a differential diagnosis to be reliable, the expert must "rule out alternative causes" by pointing to a plausible alternative cause and explaining why that alternate cause was not the sole cause. *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 759 n.27 (3d Cir. 1994). An expert need not rely on the same information for each differential diagnosis for it to be reliable because "there will be some

cases in which a physician can offer a reliable differential diagnosis without ever examining the patient, looking at medical records, taking a medical history, and performing laboratory tests." *Id.* at 762. Moreover, a court should not exclude a medical expert's causation conclusion solely because he has failed to rule out every possible alternative cause of a plaintiff's injuries. *Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 156 (3d Cir. 1999).

Here, the Court holds that Dr. Campbell reliably performed a differential diagnosis when forming his expert opinion. Dr. Campbell's expert report indicates that he reviewed Mrs. Schrecengost's pre-implant surgical history when forming his opinion. His report and testimony show that he ruled out Mrs. Schrecengost's history of endometriosis, pelvic relaxation, and vaginal lacerations as possible causes of her current dyspareunia. The record establishes that Dr. Campbell performed the differential diagnosis appropriately in reaching his conclusion that the Aris was the cause of Mrs. Schrecengost's recent dyspareunia. Defendants' concerns with Dr. Campbell's opinion are matters of weight, not admissibility. Whether Dr. Campbell's conclusion is credible is a matter for the trier of fact when Dr. Campbell is subject to cross-examination. *See In re TMI Litig.*, 193 F.3d at 665.

Accordingly, Plaintiffs have satisfied the burden under Rule 702 and Defendants' Motion to Exclude Dr. Campbell's opinion and testimony is denied.[5]

[5] The Court also holds that Dr. Campbell's report contains no errors under Rule 26 that would require exclusion of his testimony at trial. Defendants have obtained all the information required by the rule within the appropriate timelines. The Court also holds that under Rule 26, Dr. Campbell may file a supplemental or amended expert report 30 days before trial. *See* Fed. R. Civ. P. 26(a)(3)(B).

B. The Court Denies Defendants' Motion to Strike Sur-Reply and Exclude Testimony of Dr. Michael Margolis

Defendants argue that the Court should strike Plaintiffs' Sur-Reply because it fails to satisfy the basic requirements for sur-replies.[6] (ECF No. 94 at 2.) Defendants contend that Plaintiffs do not have a good faith justification for failing to abide by the deadlines and procedures of the Court's scheduling order and Federal Rules. (*Id.*) Defendants assert that Plaintiffs' late disclosure of Dr. Margolis would prejudice them because he opined that the Aris caused new injuries and there would be no feasible way to correct the prejudice without scrapping the trial schedule. (ECF No. 102 at 4.)

Plaintiffs respond that because of Mrs. Schrecengost's recent change in medical condition, Plaintiffs were within their right to have an expert such as Dr. Margolis perform an additional medical examination and opine as to the cause of Mrs. Schrecengost's recent change in condition. (ECF No. 98-1 at 7.) Defendants have failed to articulate any extreme prejudice that would necessitate striking Dr. Margolis's expert report and Plaintiffs' Sur-Reply. (*Id.*) Plaintiffs assert that Dr. Margolis's opinions do not change Plaintiffs' theory of liability in this case. (*Id.* at 7–8.) Moreover, to cure any minimal prejudice that might exist, Plaintiffs offer Dr. Margolis for deposition and would allow Defendants to conduct their own medical examination of Mrs. Schrecengost. (*Id.* at 8.)

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[6] The Court notes with disapproval the combative tone Defendants take towards Plaintiffs, their counsel, and counsel's law firm in their briefs. (*See* ECF Nos. 94, 102, 109.) For example, Defendants attack the integrity and reputation of Plaintiffs' law firm by accusing it of "gamesmanship" and "expert shopping" across the federal court system. Use of such language goes beyond mere advocacy and is not behavior the Court encourages nor finds persuasive. The Court reminds defense counsel that the Pennsylvania Code of Civility requires that all lawyers practicing in Pennsylvania speak and write in a civil and respectful manner in all communications with the court, and treat all participants in the legal process in a civil, professional, and courteous manner at all times. *See* 204 Pa. Code § 99.3(1)–(2).

The decision to strike briefing, including sur-replies, is within the sole discretion of the district court. *Venuto v. Carella, Byrne, Bain, Gilfillan, Cecchi & Stewart, P.C.*, 11 F.3d 385, 388 (3d Cir. 1993). The Court denies Defendants' motion to strike Plaintiffs' Sur-Reply because the Sur-Reply raises important issues about Mrs. Schrecengost's injuries not known to Plaintiffs at the time Plaintiffs filed their opposition to Defendants' Motion for Summary Judgment.[7] In personal injury cases such as this one, a plaintiff is not limited to recovering only the alleged damages at the date of the filing of the case, but rather can recover present and future damages resulting from her injuries attributable to the defendant. *See, e.g., Denby v. N. Side Carpet Cleaning Co.*, 390 A.2d 252, 256 (Pa. Super. Ct. 1978). Plaintiffs are not raising new theories of liability in the Sur-Reply. Whether the Court should exclude the expert disclosure contained in the Sur-Reply is a separate issue.

A party who fails to disclose a witness or expert report as either Rule 26 or court order requires may not use that information at trial unless the failure to disclose was substantially justified or is harmless. Fed. R. Civ. P. 37(c)(1). The imposition of such sanctions for abuse of discovery under Rule 37 is a matter within the discretion of the trial court. *Newman v. GHS Osteopathic, Inc., Parkview Hosp. Div.*, 60 F.3d 153, 156 (3d Cir. 1995).

The exclusion of evidence or testimony is an "extreme" sanction, not normally to be imposed absent a showing of "willful deception" or "flagrant disregard" of a court order. *Konstantopoulos v. Westvaco Corp.*, 112 F.3d 710, 719 (3d Cir. 1997). In deciding whether to exclude

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[7] Moreover, the Court would have granted Plaintiffs leave to file their Sur-Reply had they filed the appropriate motion. However, Plaintiffs are instructed to follow this Court's practices and procedures for all future filings. *See* Practices and Procedures of Judge Kim R. Gibson at 2, https://www.pawd.uscourts.gov/sites/pawd/files/JG-Practices-Procedures.pdf ("[R]eply briefs and sur-replies are not to be filed without leave of Court.")

an untimely witness, courts consider: (1) the actual prejudice or surprise of the party against whom the proffered witnesses would testify, (2) the ability of that party to cure the prejudice, (3) the extent to which waiver of the rule against calling unlisted witnesses would disrupt the orderly and efficient trial of the case or other cases in the court, (4) bad faith or willfulness in failing to comply with the district court's order, and (5) the importance of the proffered witness's testimony. *Id.*

Here, the Court holds that the disclosure of Dr. Margolis's report does not prejudice Defendants and that the timing of Plaintiffs' disclosure is substantially justified. Mrs. Schrecengost's change in medical condition justified a new medical examination. Plaintiffs timely notified Defendants of the examination and put Defendants on notice that Plaintiffs might retain a new expert to testify to the extent of Mrs. Schrecengost's worsened condition. The record establishes that Plaintiffs retained Dr. Margolis out of necessity—not to ambush Defendants. Defendants have not shown that Plaintiffs' explanation for the late disclosure is unjustified.

Defendants have also failed to show how Plaintiffs' late disclosure of Dr. Margolis will prejudice them or disrupt the trial schedule. Defendants have sufficient time to depose Dr. Margolis before trial and Plaintiffs have stated their willingness to arrange such a deposition. Defendants also have sufficient time to move to exclude his testimony if they believe they have grounds to do so. Defendants have not shown that this disclosure was made in bad faith or that they had no notice of Dr. Margolis's examination of Mrs. Schrecengost before the disclosure was made in the Sur-Reply.

Accordingly, the Court will not strike Plaintiffs' Sur-Reply or the opinions and testimony of Dr. Margolis.

C. The Court Denies Defendants' Motion for Summary Judgment

Defendants have moved for summary judgment on all of Plaintiffs claims, which are: (1) negligent design defect, (2) negligent failure to warn, (3) strict liability – defective design, (4) strict liability – failure to warn, and (5) loss of consortium. The Court will address each in turn.

1. Plaintiffs Can Establish that Defendants Negligently Designed the Aris

Defendants argue that Plaintiffs' negligent design claim fails for lack of evidence of causation and existence of an alternative design. Defendants argue that Plaintiffs lack the specific-causation evidence necessary to sustain their negligent design claim because Dr. Campbell's opinions are unreliable and the Court should exclude them. (ECF No. 80 at 2.) Moreover, Plaintiffs have no evidence of any feasible safer alternative design, which is an essential element of Plaintiffs' claim. (*Id.*) Defendants contend that Dr. Rosenzweig's proffered safer alternatives are actually entirely different products because they are not polypropylene surgical mesh implants indicated and cleared to treat SUI. (*Id.* at 3.) Specifically, the Ultrapro is not a safer alternative because it is not indicated for surgical treatment of SUI and Defendants therefore could not have practically adopted it. (*Id.* at 4.)

Plaintiffs respond by stating that they can establish all the required elements of their claim. Plaintiffs assert that they have shown that there is a question of fact that the Aris proximately caused Mrs. Schrecengost's injuries. (ECF No. 73 at 8.) Plaintiffs argue that Dr. Rosenzweig testified that the Aris is capable of producing significant injuries and that Dr. Campbell testified that the Aris specifically caused Mrs. Schrecengost's injuries. (*Id.* at 8–9.) Dr. Margolis's

testimony would also establish that the Aris caused Mrs. Schrecengost's injuries. (ECF No. 92 at 3.)

Plaintiffs assert that showing the existence of a safer alternative design is not an element for a negligent design defect claim under Pennsylvania law, but that the alternative designs can show that other designs existed to establish Defendants' negligence. (ECF No. 73 at 10.) Plaintiffs assert that Defendants could have used an absorbable mesh to minimize the risks associated with nonabsorbable mesh slings like the Aris. (*Id.* at 11.) Plaintiffs argue that Defendants knew prior to Mrs. Schrecengost's Aris surgery that additional alternative designs existed, including lighter weight mesh alternatives, such as the Ultrapro. (*Id.* at 11–12.) Additionally, several doctors warned Defendants in 2008 about the relationship between using heavier weight mesh and increased erosion rates. (*Id.* at 12.)

To establish a negligent design claim in Pennsylvania, a plaintiff must demonstrate that the defendant breached its duty of care in designing the product, and that the breach caused her injuries. *Phillips v. Cricket Lighters*, 841 A.2d 1000, 1008 (Pa. 2003). To establish a breach of a duty of care, plaintiffs may, but are not required to, present evidence of a safer alternative design that the defendant could have adopted. *Tincher v. Omega Flex, Inc.*, 104 A.3d 328, 398 (Pa. 2014); *Lance v. Wyeth*, 85 A.3d 434, 458 n.36 (Pa. 2014). To establish proximate cause, plaintiffs must introduce expert testimony to show that: (1) the product at issue is capable of causing the alleged injury (general causation), and (2) the product did in fact cause the plaintiff's alleged injury (specific causation). *Soldo v. Sandoz Pharm. Corp.*, 244 F. Supp. 2d 434, 525 (W.D. Pa. 2003) (applying Pennsylvania law).

Here, the Court holds that Plaintiffs have introduced sufficient evidence for a jury to conclude that Defendants breached their duty of care owed to Mrs. Schrecengost by negligently designing a defective product. Plaintiffs can show that Defendants were aware of medical risks of injury from the Aris because of the heavier weight mesh the Aris used. Moreover, Plaintiffs can show that Defendants were aware that other types of lighter mesh were on the market and would have reduced the risks of injury by using these alternatives. Plaintiffs can show that alternative devices that can treat SUI without using the heavier weight mesh that the Aris used existed, such as the Ultrapro. Dr. Rosenzweig explained that alternative, lighter weight, large-pore mesh designs, such as Ultrapro, would have decreased the medical risks associated with smaller-pore, heavier weight polypropylene mesh. Plaintiffs need not present an alternative design that is identical in every respect to Defendants' product, but instead Plaintiffs can use the designs to show that there were feasible alternative ways to more safely treat SUI and that Defendants were negligent for failing to use those methods and designs.

Additionally, the Court holds that Plaintiffs could convince a reasonable jury that the Aris proximately caused Mrs. Schrecengost's injuries. Dr. Rosenzweig determined that the Aris could cause significant injuries because its mesh can degrade over time and can lead to complications in patients. He found that these complications include chronic and debilitating pelvic pain, chronic dyspareunia, rejection of the mesh, sexual dysfunction, and the need for additional surgeries. Moreover, the Court finds that Dr. Campbell and Dr. Margolis each provide sufficient and independent expert testimony to establish that the Aris specifically caused Mrs. Schrecengost's injuries. Dr. Campbell testified that Mrs. Schrecengost's dyspareunia was caused by the Aris and ruled out other possible causes of her pelvic pain for his differential diagnosis.

Dr. Margolis found in his examination that Mrs. Schrecengost is suffering from several complications that defects in the Aris caused.

Accordingly, the Court holds that Plaintiffs can satisfy their burden of proof for their negligent design defect claim.

2. Plaintiffs Can Establish that Defendants Negligently Failed to Warn Dr. David of All of the Aris's Medical Risks

Defendants argue that Plaintiffs' claim for negligent failure to warn fails because they have no evidence that Mrs. Schrecengost's alleged injuries were proximately caused by any defect in the warnings included with the Aris when Dr. David treated her SUI. (ECF No. 64 at 18.) Moreover, the learned-intermediary doctrine bars Plaintiffs' claim because Dr. David testified that he did not recall reviewing the Aris IFU prior to Mrs. Schrecengost's surgery and because Dr. David was independently aware of the risks of the injuries that Mrs. Schrecengost alleges that she suffered as a result of the Aris. (*Id.* at 18–19.) Defendants assert that Dr. David would not have changed his behavior when treating Mrs. Schrecengost because he still uses the Aris to treat SUI. (*Id.* at 19.)

Plaintiffs assert that Defendants failed to include, or downplayed, significant risks in their IFU for the Aris. (ECF No. 73 at 15.) Dr. Rosenzweig found that Defendants' IFUs did not include sufficient information to advise physicians on the permanence, frequency, and severity of the complications that could arise from the use of its devices. (*Id.*) Plaintiffs assert that Defendants were aware of these risks because Defendants' paid consultants expressed concerns about safety issues associated with the Aris to them. (*Id.*) Plaintiffs argue they can establish causation because Dr. David testified that he read and relied on the IFUs in counseling his patients regarding risks

associated with the device. (*Id.* at 16.) Plaintiffs argue that although Dr. David may have been aware of general risks that accompany any pelvic floor surgery, Defendants failed to inform him not only of the specific risks associated with the Aris, but also the frequency, severity, and permanency of those risks. (Id. at 17.) His general surgical knowledge was not enough to communicate the specific risks of the Aris to Mrs. Schrecengost so that she could accurately weigh the risks and benefits of the surgery herself. (*Id.*)

To establish a negligent failure to warn claim under Pennsylvania law, a plaintiff must demonstrate that the defendant breached its duty to warn, and that the breach caused her injuries. *Taurino v. Ellen*, 579 A.2d 925, 927 (Pa. Super. Ct. 1990). In the context of claims alleging a negligent failure to warn about the risks of a medical device, the manufacturer's duty is to adequately warn the treating physician. *Simon v. Wyeth Pharm.*, 989 A.2d 356, 368 (Pa. Super. Ct. 2009).

For a warning to be adequate as a matter of law under Pennsylvania law, it must: (1) accurately and unambiguously convey the scope and nature of the risk, and (2) state the risk with sufficient specificity. *Rowland v. Novartis Pharm. Corp.*, 34 F. Supp. 3d 556, 572 (W.D. Pa. 2014) (applying Pennsylvania law). A warning of a particular risk is not adequate as a matter of law, even when that warning is accurate, if there are disputes over whether the warning was sufficiently explicit and detailed. *Id.; see e.g., Maya v. Johnson & Johnson*, 97 A.3d 1203, 1215 (Pa. Super. Ct. 2014) (holding that a warning to call a doctor if complications arose was not an adequate warning because it did not tell the user to stop taking the drug). To determine if a warning is adequate as a matter of law, courts look to the warning itself and what the defendant

knew or should have known about a given risk at the time of an alleged injury. *Rowland*, 34 F. Supp. 3d at 572.

To establish that a failure to warn about the risks of a medical device was a proximate cause of an injury, a plaintiff must show that had the defendant issued a proper warning to the prescribing physician, the warning would have altered the physician's behavior or treatment and the injury would have been avoided. *Demmler v. SmithKline Beecham Corp.*, 671 A.2d 1151, 1155 (Pa. Super. Ct. 1996). The plaintiff must introduce evidence that shows some reasonable likelihood that an adequate warning would have prevented the plaintiff from undergoing the course of treatment in question. *Id.*

Here, the Court holds that the Aris's warnings are not, as a matter of law, adequate and that the adequacy of the warnings is a proper question for the jury. The parties dispute which risks Defendants knew about the Aris and whether Defendants disclosed all these relevant risks to Dr. David. Plaintiffs can show that Defendants were aware of medical concerns with the Aris that were not disclosed in the IFU, such as its risk of erosion and degradation.

Additionally, Plaintiffs can show that Defendants' failure to warn of the Aris's risks were the proximate cause of Mrs. Schrecengost's injuries. Plaintiffs can show that there are risks regarding the use of the Aris that Defendants did not disclose to treating physicians, such as Dr. David. There is a dispute as to whether Dr. David reviewed the Aris IFU before Mrs. Schrecengost's surgery. Dr. David stated that he expects IFU warnings to list any potential complications, as well as their frequency or severity, and that he would have changed his treatment recommendations if he had known about certain risks because he would have informed his patients of those risks. Mrs. Schrecengost testified that had she known about these other risks,

she would have declined the surgery. Therefore, a jury could find that Mrs. Schrecengost's injuries could have been avoided had Defendants properly warned Dr. David of the Aris's risks.

Accordingly, the Court holds that Plaintiffs can satisfy their burden of proof for their negligent failure to warn claim.

3. Strict Liability Design Defect and Failure to Warn Claims Are Cognizable in Pennsylvania

The parties contest whether Pennsylvania law recognizes strict liability claims against medical device manufacturers like Defendants. The Pennsylvania Supreme Court has not ruled definitively on the issue. In the absence of a decision from the Pennsylvania Supreme Court, this Court must predict how the Pennsylvania Supreme Court would rule on this issue. *See Berrier v. Simplicity Mfg., Inc.*, 563 F.3d 38, 45–46 (3d Cir. 2009). A federal district court in this position should consider "relevant state precedents, analogous decisions, considered dicta, scholarly works, and any other reliable data tending convincingly to show how the highest court in the state would decide the issue at hand." *Id.* at 46 (quoting *McKenna v. Ortho Pharm. Corp.*, 622 F.2d 657, 663 (3d Cir. 1980)). From the sources available, it appears that the Pennsylvania Supreme Court would permit a cause of action against medical device manufacturers—specifically manufacturers of surgical mesh implants—under design defect and failure to warn theories of strict liability.

The Court finds the Pennsylvania Supreme Court's discussion of strict liability in *Tincher v. Omega Flex, Inc.*, 104 A.3d 328 (Pa. 2014) persuasive and an indication of how that court would rule on this issue. In *Tincher*, the court clarified Pennsylvania law regarding strict liability claims. The court first explained at length that under Pennsylvania law "[n]o product is expressly exempt

[from strict liability] and, as a result, the presumption is that strict liability may be available with respect to any product, provided that the evidence is sufficient to prove a defect." *Id.* at 382 (citing Restatement (Second) of Torts § 402A cmt. B (Am. Law Inst. 1975)). The Supreme Court cautioned courts in Pennsylvania from making categorical exemptions of immunity from strict liability:

> Courts, which address evidence and arguments in individual cases, are neither positioned, nor resourced, to make the kind of policy judgments required to arrive at an *a priori* decision as to which individual products, or categories and types of products, should be exempt. Neither courts, nor the American Law Institute for that matter, are in the business of articulating general principles tailored to anoint special "winners" and "losers" among those who engage in the same type of conduct. In our view, the question of "special tort-insulated status" for certain suppliers—for example, manufacturers of innovative products with no comparable alternative design—optimally "requires an assessment and balancing of policies best left to the General Assembly."

Id. at 396 (quoting *Scampone v. Highland Park Care Ctr., LLC*, 57 A.3d 582, 599 (Pa. 2012)). The court clarified that where no immunity from strict liability exists under the common law, or where the Pennsylvania General Assembly has not created immunity, "the default general rule of possible liability operates."[8] *Id.* (internal quotation marks omitted) (quoting *Scampone*, 57 A.3d at 599).

The court next addressed the Second Restatement's relation to Pennsylvania common law. It stated that although Pennsylvania courts follow the Second Restatement, "adoption" of Restatement principles into Pennsylvania common law requires a separate analysis. *Id.* at 399. Further, it stated that the text and comments of the Second Restatement are not binding on Pennsylvania courts, nor are they entitled to as great of weight as legislative pronouncements would receive. *Id.* The court reasoned that a "principal point" of its decision is that Pennsylvania

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[8] The court noted that the General Assembly has not spoken affirmatively in relation to strict liability cause of action and strict liability claims have remained a creature of common law. *Tincher*, 104 A.3d at 381 n.18.

courts should "permit the common law to develop incrementally, as we provide reasoned explications of principles pertinent to factual circumstances of the cases that come before the Court." *Id.* at 406 (citing *Scampone*, 57 A.3d at 605). Consistent with the changing nature of the common law, the court noted that its decision "may have an impact upon other foundational issues" of strict liability law, observing that although "[o]ur decision is limited to the context of a 'design defect' claim by the facts . . . the foundational principles upon which we touch may ultimately have broader implications by analogy." *Id.* at 384 n.21, 409.

Although not cited in the opinion, *Tincher*, on its face, affects how Pennsylvania courts apply comment k of § 402A of the Second Restatement. That comment exempts certain products from strict liability, stating:

> There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs . . . . Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous.

Restatement (Second) of Torts, § 402A cmt. k. The Pennsylvania Supreme Court has adopted comment k to exempt prescription drugs from the imposition of strict liability on manufacturers selling these drugs. *Hahn v. Richter*, 673 A.2d 888, 889–90 (Pa. 1996).

In *Creazzo v. Medtronic, Inc.*, 903 A.2d 24 (Pa. Super. Ct. 2006), the Superior Court noted, after determining that no significant distinction could be drawn between the medical device before the court and the drug in *Hahn*, that there was "no reason why the same rational[e] applicable to prescription drugs may not be applied to medical devices." *Id.* at 31. Defendants assert that *Creazzo* closed the door for all strict liability claims against medical device manufacturers in Pennsylvania.

Defendants' reliance on *Creazzo* and *Hahn* is misplaced. First, *Creazzo*'s application of *Hahn* to medical devices does not reflect the law in Pennsylvania. Since the Superior Court's decision in 2006, the Pennsylvania Supreme Court has never cited, relied on, adopted, or even addressed *Creazzo*'s rationale that medical device manufacturers cannot be subject to strict liability claims.[9] *Accord Wagner v. Kimberly-Clark Corp.*, 225 F. Supp. 3d 311, 317 (E.D. Pa. 2016). This lack of acknowledgement by the Pennsylvania Supreme Court in cases concerning strict liability claims against medical device manufacturers casts the *Creazzo* decision into doubt. *See, e.g., Beard v. Johnson & Johnson, Inc.*, 41 A.3d 823, 824 (Pa. 2012).

Second, the Pennsylvania Supreme Court would likely decline to adopt *Creazzo*'s rationale. The Pennsylvania Supreme Court has rejected invitations to change common law duties without presentation of a "full and balanced record covering the range of relevant policy matters." *Lance v. Wyeth*, 85 A.3d 434, 455 (Pa. 2014); *see also Seebold v. Prison Health Servs.*, 57 A.3d 1232, 1247 (Pa. 2012). There is no indication that the parties presented a full and balanced record of policy considerations to the court in *Creazzo*. In fact, the opposite was true. The court acknowledged that the appellants, who were pro se, offered no analysis or authority for a different interpretation of *Hahn*. *See Creazzo*, 903 A.2d at 31. Because no analysis of the relevant policy issues concerning strict liability immunity for medical device manufacturers was squarely placed before the *Creazzo* court, the Pennsylvania Supreme Court would likely not adopt its holding without more analysis. As *Tincher* made clear, the principles of the Restatement must be adopted into Pennsylvania common law and there is no dispute that the Pennsylvania Supreme

[9] In fact, *Creazzo* has only been cited once in a footnote by the Pennsylvania Supreme Court. *See Pyeritz v. Commonwealth*, 32 A.3d 687, 692 n.5 (Pa. 2011). That citation referred to the principle of spoliation of evidence, a separate aspect of the *Creazzo* case from the strict liability issue. *Id.*

Court has not applied comment k to shield medical device manufacturers from strict liability. *See Tincher*, 104 A.3d at 399.

Third, Defendants do not justify the imposition of strict liability immunity in this case by comparing the facts of this case to *Creazzo* and *Hahn*. The Supreme Court has instructed that holdings of a judicial decision must be read in relation to its facts. *See Lance*, 85 A.3d at 453. Defendants here do not analogize the Aris to either the drug in *Hahn* or the medical device in *Creazzo*. Defendants assert that because the Aris is a medical device, they are immune from strict liability claims. Defendants invite this Court to create a special tort-insulated status for medical device manufacturers, the kind of categorical pronouncement the *Tincher* court instructed Pennsylvania courts to avoid. *See Tincher*, 104 A.3d at 396. The Court declines to make such a pronouncement and reserves that issue for the Pennsylvania Supreme Court and Pennsylvania General Assembly. In the absence of a shield of strict liability immunity granted by the Pennsylvania Supreme Court or Pennsylvania General Assembly, the Court defers to the general rule in Pennsylvania that no product is immune from strict liability. This includes products such as the Aris.

Fourth, even if comment k applied here, the interpretation and application of comment k is no straightforward task for a court. The Pennsylvania Supreme Court itself has struggled with it, stating that "comment k is not itself a model of clarity." *Lance*, 85 A.3d at 451. For example, it is unclear how courts should decide whether a product is "unavoidably unsafe" or "properly prepared." *See, e.g., Wagner*, 225 F. Supp. 3d at 317. It is also unclear whether comment k would be a categorical shield of immunity or one for a court to assess on a case by case basis by comparing the utility of a product to its unavoidably dangerous propensities. *See id.* As noted in

Tincher, these are policy decisions that require careful consideration more suited for a legislature. *See Tincher*, 104 A.3d at 396.

The Court recognizes that other federal courts in this Circuit, including this Court, have predicted that the Pennsylvania Supreme Court would not recognize these causes of action. *See, e.g., Wilson v. Synthes USA Prods., LLC*, 116 F. Supp. 3d 463, 465–66 (E.D. Pa. 2015); *Cogswell v. Wright Med. Tech., Inc.*, No. 1:15-cv-295, 2015 WL 4393385, at *2 (W.D. Pa. July 16, 2015); *Stout v. Advanced Bionics, LLC*, No. 2:11-cv-1061, 2013 WL 12133966, at *8 (W.D. Pa. Sept. 19, 2013); *McPhee v. DePuy Orthopedics*, 989 F. Supp. 2d 451 (W.D. Pa. 2012); *Kee v. Zimmer, Inc.*, 871 F. Supp. 2d 405, 409 (E.D. Pa. 2012); *Soufflas v. Zimmer, Inc.*, 474 F. Supp. 2d 737, 750 (E.D. Pa. 2007); *Parkinson v. Guidant Corp.*, 315 F. Supp. 2d 741, 747 (W.D. Pa. 2004). However, these decisions were either made before *Tincher* was decided in 2014 or did not interpret and apply *Tincher*, which the Court interprets as an implicit recognition by the Pennsylvania Supreme Court that these strict liability claims are cognizable against medical device manufacturers like Defendants. Defendants' citation to these decisions does not change this Court's analysis of the issue.

As the law stands, neither the Pennsylvania Supreme Court nor the Pennsylvania General Assembly have created immunity from strict liability for medical device manufacturers like Coloplast. Accordingly, since the claims are cognizable, the Court turns to evaluating whether Plaintiffs can proceed to trial with their strict liability claims.

4. Plaintiff's Strict Liability Claims

In Pennsylvania, a seller is strictly liable for physical harm caused by "any product in a defective condition unreasonably dangerous to the user or consumer." *Webb v. Zern*, 220 A.2d 853, 854 (Pa. 1966) (citing Restatement (Second) of Torts § 402A). Unlike a negligence claim,

which examines the conduct and fault of the defendant, strict liability claims examine the quality of the product itself. See 578 A.2d 492, 501. Pennsylvania has recognized three types of defective conditions that can give rise to strict liability: design defect, manufacturing defect, and failure to warn defect. *Phillips v. A-Best Prods. Co.*, 665 A.2d 1167, 1170 (Pa. 1995).

Here, Plaintiffs have alleged design defect and failure to warn defect strict liability claims. The Court will address each in turn.

a. Plaintiffs Can Establish that Defendants Are Strictly Liable for the Aris's Design Defect

To prevail on a strict products liability claim, a plaintiff must show that: (1) the product was in a defective condition, (2) the defect was a proximate cause of the plaintiff's injuries, and (3) that the defect causing the injury existed at the time the product left the defendant's control. *Davis v. Berwind Corp.*, 690 A.2d 186, 190 (Pa. 1997). A plaintiff may prove defective condition by showing either that: (1) the danger is unknowable and unacceptable to the average or ordinary consumer (consumer expectations standard), or that (2) a reasonable person would conclude that the probability and seriousness of harm caused by the product outweigh the burden or costs of precautions that the defendants could take (risk-utility standard). *Tincher*, 104 A.3d at 335. A defective product is a proximate cause of the plaintiff's harm if the product "was a substantial factor in bringing about the harm inflicted upon a plaintiff." *Jones v. Montefiore Hosp.*, 431 A.2d 920, 923 (Pa. 1981).

Here, Plaintiffs can show that the Aris was defective under either the consumer expectations standard or the risk-utility standard. Dr. Rosenzweig testified that the public did not know about the danger of erosion or degradation of the Aris mesh, and Plaintiffs can show

that this risk of injury would be unacceptable to an ordinary consumer. For example, Mrs. Schrecengost has stated that had Dr. David told her of all of the risks of the Aris surgery, she would not have agreed to it. Dr. Rosenzweig also testified that the probability and seriousness of the injuries the Aris could cause outweighed Defendants' burden to follow other safer designs that used an absorbable, lighter pore mesh. Additionally, Plaintiffs can show that the Aris was a proximate cause of Mrs. Schrecengost's injuries because Dr. Campbell and Dr. Margolis have testified that the defects of the Aris specifically caused those injuries.

Accordingly, the Court holds that Plaintiffs can satisfy their burden for their design defect claim under a theory of strict liability.

b. Plaintiffs Can Establish that Defendants Are Strictly Liable for Failing to Warn About the Aris's Risks

To prevail on a strict products liability claim, a plaintiff must show that: (1) the product was in a defective condition, (2) the defect was a proximate cause of the plaintiff's injuries, and (3) the defect causing the injury existed at the time the product left the defendant's control. *Davis*, 690 A.2d at 190. A product can be considered "defective" for strict liability purposes if it is distributed without warnings sufficient to notify the ultimate user of the dangers inherent in the product. *Id.* A defective product is a proximate cause of the plaintiff's harm where the product "was a substantial factor in bringing about the harm inflicted upon a plaintiff." *Jones*, 431 A.2d at 923.

Here, for the reasons discussed previously, the Court holds that the Aris's warnings are not, as a matter of law, adequate. *See supra* Section VI.C.2. The Court also holds that a reasonable jury could find that the lack of warnings was a substantial factor in Mrs. Schrecengost's injuries.

Plaintiffs can show that had Mrs. Schrecengost known about these additional risks, she would not have agreed to the surgery.

Accordingly, the Court holds that Plaintiffs can satisfy their burden for their failure to warn claim under a theory of strict liability.

5. Plaintiffs Can Maintain Mr. Schrecengost's Loss of Consortium Claim

Defendants argue that because Mrs. Schrecengost's claims fail, Mr. Schrecengost's derivative loss of consortium claim fails as it cannot exist as a freestanding claim. (ECF No. 64 at 20.) Plaintiffs assert that Mr. Schrecengost's loss of consortium claim does not fail because Mrs. Schrecengost's claims survive summary judgment. (ECF No. 73 at 25.)

The Court holds that because Plaintiffs maintain claims other than the loss of consortium claim, dismissal of this claim is not warranted.

VII. Conclusion

For the forgoing reasons, the Court denies Defendants' Motion to Exclude Opinions and Testimony of Dr. Grant Campbell, Motion to Strike Plaintiffs' Proposed Sur-Reply and to Exclude from Trial the Untimely Expert Opinions of Dr. Michael Margolis, and Motion for Summary Judgment.

An appropriate order follows.

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

DEBORAH SCHRECENGOST and ROGER SCHRECENGOST,	)	Case No. 3:17-cv-220
Plaintiffs,	)	JUDGE KIM R. GIBSON
v.	)	
COLOPLAST CORPORATION and COLOPLAST MANUFACTURING US, LLC,	)	
Defendants.	)	

ORDER

AND NOW, this 2ND day of December, 2019, upon consideration of Defendants' Motion to Exclude Opinions and Testimony of Dr. Grant Campbell (ECF No. 61), Motion to Strike Plaintiffs' Proposed Sur-Reply and to Exclude from Trial the Untimely Expert Opinions of Dr. Michael Margolis (ECF No. 93), and Motion for Summary Judgment (ECF No. 63.), and for the reasons set forth in the accompanying Memorandum Opinion, it is **HEREBY ORDERED** that said Motions are **DENIED**.

BY THE COURT:

KIM R. GIBSON
UNITED STATES DISTRICT JUDGE